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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,815	07/09/2001	Lars Lannfelt	LANNFELT1A	9645

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BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER
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CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/19/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/899,815

Applicant(s)

LANNFELT ET AL.

Examiner

Olga N. Chernyshev

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1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 8-15 and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) 8-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

## DETAILED ACTION

### *Status of the claims*

1. Claims 8, 17 and 19 have been amended, claims 22-23 have been added and claims 1-7 and 16 have been cancelled as requested in the amendment of Paper No. 15, filed on September 03, 2002.

Claims 8-15 and 17-23 are pending in the instant application.

### *Election/Restrictions*

2. Applicant's election without traverse of Group VIII in Paper No. 15 is acknowledged.

Claims 8-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 15.

Claims 17-23 are under examination in the instant office action.

### *Sequence compliance*

3. The text on pages 5, last paragraph, and 7, third paragraph is not in compliance with the requirements for Sequence Identifiers (see MPEP 2422.03). The appropriate format for sequence identifiers is SEQ ID NO:X, wherein "X" is the sequence number. Appropriate correction is required.

Applicant is advised to review the entire text if the instant specification for proper use of sequence identifiers.

***Priority***

4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

***Oath/Declaration***

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of inventor Lannfelt.

***Drawings***

6. The figures of the instant application are presented in separate panels. 37 C.F.R. § 1.84(u) (1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. For example, the three panels of Figure 1 in the instant specification should be renumbered “Figure 1A” – “Figure 1C” rather than “Figure 1a, b, c”. Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(u) (1), the specification should be amended to change the Brief Description of the Drawings and the rest of the specification to refer to each Figure accordingly. If, for example, Figure 1 is divided into Figures 1A-1C, then the Brief Description and all the references to this figure in the specification must refer to this Figure in the same manner.

### ***Specification***

7. The use of the trademarks has been noted in this application, see page 12, last line and page 13, line 3, for example. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Objections***

8. Claims 18 and 19 are objected to because of the following informalities:  
“immunisation”, should be “immunization”, perhaps. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 17-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the method steps of achieving prevention or treatment of AD.

Applicant is advised that “decreasing the formation of A $\beta$  protofibrils and/or lower meric forms thereof in a subject” constitutes a goal achieved by the claimed method and not a method step itself. It is vague and indefinite what are the means or the claimed method steps of achieving the decrease of the formation of A $\beta$  protofibrils.

Claim 17 is further vague and indefinite for recitation of “decreasing the formation of A $\beta$  protofibrils”. Decrease is a relative term and, unless the degree of such decrease is defined, the claimed subject matter remains ambiguous.

11. Claim 18 is indefinite for recitation of “enhanced protofibril forming ability” and “enhanced immunogenicity”. Enhancement is a relative term and no point of reference is given. Therefore, it is not clear what level of enhancement is intended by the claim.

12. Claim 20 is vague and ambiguous for recitation of “agents with anti-prototofibrillar activity”. The metes and bounds of the recitation cannot be determined from the claims.

13. Claim 21 is indefinite because it does not make sense.

14. Claim 22 is indefinite for recitation of residues 16-24 of normal A $\beta$  peptide and following such recitation with a SEQ ID number that relates to Arctic mutation of A $\beta$ . The subject matter, which is claimed, cannot be defined from the claim.

15. Claim 23 is indefinite for being dependent from an indefinite claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 17, 18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kline et al. (WO 95/31996, 1995, Reference AC of IDS of Paper No. 12).

Claims 17, 18 and 22 are directed to a method for treatment of Alzheimer's disease by immunization with a compound(s) with protofibril forming ability. According to the instant specification, "compound(s) with protofibril forming ability comprises the following amino acid sequence KLVFFAEDV" (page 4, fifth paragraph), which is an amino acid sequence of a fragment of normal A $\beta$ . The same amino acid sequence is recited in claim 22.

Kline et al. teach a method for alleviating the symptoms of Alzheimer's disease by administration of amyloid protein or a fragment thereof, see claims 1, 2, 7 and also the Examples. Thus, the disclosure of Kline et al. meets the limitations of claims 17, 18 and 22.

17. Claims 17, 18, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Schenk (WO 99/27944, June 1999, Reference AD of IDS of Paper No. 12).

Schenk teaches a method of preventing or treating Alzheimer's disease by administration an agent effective to induce an immune response against a peptide component of an amyloid deposit in the patient, wherein the amyloid deposit comprises aggregated A $\beta$  peptide or an active fragment thereof (see claims 8, 9, 11 and 16). Schenk specifically discloses that "[t]he therapeutic agent used in the claimed methods can be any of the naturally occurring form of A $\beta$ " (page 14, lines 25-26) and it also can be "an active fragment or analog of a natural A $\beta$  peptide (page 15, lines 1-2). Therefore, A $\beta$  disclosed in Schenk document encompasses an Arctic mutation of A $\beta$  of the instant specification.

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18. Furthermore, claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Schenk (WO 99/27944, June 1999).

Claim 19 is drawn to a method for prevention or treatment of Alzheimer's disease by immunization with antibodies against compound(s) with protofibril forming activity. It is clear from the instant specification that "compound(s) with protofibril forming ability" encompass normal A $\beta$  (page 4, fifth paragraph).

Schenk teaches a method of treating an Alzheimer's disease by administration of an antibody to A $\beta$  (claim 24). Therefore, the disclosure of Schenk anticipates claim 19 of the instant application.

### *Conclusion*

19. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax



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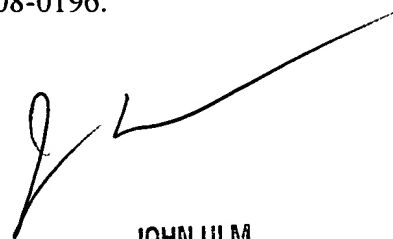
center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.  
November 15, 2002

OC



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800